

Application No. 10/792,346
Amendment dated July 7, 2006
Attorney Docket No. CV06038US01

REMARKS

Applicants are pleased to note that claim 20 has been indicated as allowable if rewritten in independent form and sincerely appreciate the suggestions to facilitate allowance of the application.

Claims 1-24 are pending in this application. Claims 10 and 11 have been withdrawn by the Examiner as being drawn to a non-elected invention. Claims 1, 9, 12, 21 and 23 have been amended. The amendments to the abstract and claims 1, 9, 12, 21 and 23 are supported in the specification, such as at page 17, line 23 through page 23, line 2. No new matter has been added to the application by any of the foregoing amendments.

Restriction Requirement and Provisional Election

A three-way restriction requirement was set forth at pages 2-3 of the Office Action. For brevity, these rejections are not repeated herein but reference is made to the Office Action.

Applicants respectfully traverse the restriction requirement and request that the rejection be reconsidered and withdrawn.

At page 2 of the Office Action, it is alleged that sugars and peptides are structurally dissimilar to the other organic groups recited. Applicants assert that there is no undue burden to search the subject matter of each of the Groups (I – III) due to the main core of the molecule being similar to all of the groups of compounds. Therefore, reconsideration and withdrawal of the restriction requirement and election of species requirement is respectfully requested.

To facilitate prosecution of the application and in order to comply with the Examiner's requirements, Applicants hereby provisionally elect with traverse the claims of Group I (claims 1-9 and 12-24) for initial examination in this application.

Rejections Under 35 USC § 112

At pages 3-5 of the Office Action, claims 1-9, 12-19 and 21-24 have been rejected under 35 USC § 112, second paragraph, for alleged indefiniteness regarding:

- (1) C₀ alkylene;

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- (2) Substitution of groups such as alkyl;
- (3) $-\text{N}-\text{N}=\text{N}^+$;
- (4) Meaning of the term "diabetes";
- (5) Meaning of the term "sterol"; and
- (6) Meaning of the term "stanol".

Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Regarding item (1) above, one skilled in the art would understand that $-(\text{C}_0-\text{C}_{10})$ alkylene)-G, for example, means that the alkylene moiety is not present when C is zero, i.e., there is a covalent bond between the main molecule and G, i.e., -G. If C is one, then the group would be $-\text{CH}_2\text{G}$, for example. While Applicants respectfully disagree with the rejection, to expedite examination of the application Applicants have amended claim 1 to delete reference to C_0 and instead show these moieties as, for example, -G.

Regarding item (2), while Applicants respectfully disagree with the rejection, to expedite examination Applicants have amended claim 1 to specify that each of the alkyl, alkenyl, alkynyl, alkylene, alkoxyalkoxy, alkoxyalkoxyalkoxy, alkoxy carbonylalkoxy, alkoxyarylalkoxy, alkoxyiminoalkyl, alkyldioyl, allyloxy, aryl, arylalkyl, aryloxy, arylalkoxy, aroyl, aroyloxy, aroylaroyloxy, arylalkoxycarbonyl, benzoylbenzoyloxy, heteroaryl, heteroarylalkyl, heteroarylalkoxy, dioxolanyl, heterocyclyl, heterocyclylalkyl, heterocyclylcarbonyl, or heterocyclylcarbonylalkoxy groups, when present, is independently substituted or unsubstituted. This amendment is supported in the description of each moiety in the specification at page 20, line 1 through page 25, line 5.

Regarding item (3), Applicants have amended claim 1 to clarify that the azido moiety was intended.

Regarding item (4), the meaning of the term diabetes is intended to be inclusive and is well known to those skilled in the art. While Applicants respectfully disagree with the rejection, to expedite examination Applicants have amended claim 1 to specify diabetes mellitus, as discussed at page 1, line 18 of the specification.

Regarding item (5), the term "sterol" is explained in the specification at page 47, lines 24-26 as including cholesterol and phytosterols, such as sitosterol, campesterol,

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stigmasterol and avenosterol and mixtures thereof. While Applicants respectfully disagree with the rejection, to expedite examination of the application claims 20 and 22 have been amended to cholesterol and phytosterols.

Regarding item (6), the term "stanol" is explained in the specification at page 47, lines 25-27 as including 5 α -stanols, such as cholestanol, 5 α -campestanol, and 5 α -sitostanol and mixtures thereof. While Applicants respectfully disagree with the rejection, to expedite examination of the application claims 20 and 22 have been amended to 5 α -stanols.

None of the foregoing amendments were made for any prior art reasons. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

At page 5 of the Office Action, claims 1-9, 12-19 and 21-24 have been rejected under 35 USC § 112, paragraphs 1 and 2, for lack of written description and lack of enablement for trialkylammonium alkyl radical. Applicants respectfully traverse and request reconsideration and withdrawal of this rejection. Applicants wish to point out that claim 1 includes pharmaceutically acceptable salts of the compound of Formula (I). Please see page 24, line 28 – page 25, line 9 for a discussion of suitable acids for salt formation and description of formation of the salts. In view of the claim language and disclosure in the specification, one skilled in the art can readily ascertain the meaning of salt of trialkylammonium alkyl. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

At pages 6-12 of the Office Action, claim 23 has been rejected under 35 USC § 112, first paragraph, for lack of written description or enablement as to the treatment of the disorders listed. Applicants respectfully traverse and request reconsideration and withdrawal of this rejection. While Applicants respectfully disagree with the rejection, to expedite examination of the application Applicants have amended claim 23 to specify vascular conditions, etc. without prejudice to the filing of one or more divisional applications directed to the amended subject matter. This amendment was not made for any prior art reasons. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

In view of the remarks above, reconsideration and withdrawal of the rejections, and favorable allowance of all claims is respectfully requested. Should the Examiner have any questions or wish to discuss this matter further, he is invited to contact Applicant's representative at 412-471-8815.

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Respectfully submitted,

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